

## Food and Drug Administration, HHS

## § 882.1825

electronic processing equipment for measuring and displaying the nerve conduction time.

(b) *Classification*. Class II (performance standards).

### § 882.1560 Skin potential measurement device.

(a) *Identification*. A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

(b) *Classification*. Class II (performance standards).

### § 882.1570 Powered direct-contact temperature measurement device.

(a) *Identification*. A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

(b) *Classification*. Class II (performance standards).

### § 882.1610 Alpha monitor.

(a) *Identification*. An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

(b) *Classification*. Class II (performance standards).

### § 882.1620 Intracranial pressure monitoring device.

(a) *Identification*. An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

(b) *Classification*. Class II (performance standards).

### § 882.1700 Percussor.

(a) *Identification*. A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807

of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 59 FR 63011, Dec. 7, 1994]

### § 882.1750 Pinwheel.

(a) *Identification*. A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

### § 882.1790 Ocular plethysmograph.

(a) *Identification*. An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17739, May 11, 1987]

### § 882.1825 Rheoencephalograph.

(a) *Identification*. A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any rheoencephalograph that was